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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,072	09/19/2003	Olivier Courtin	146.1341-DIV.	7666
47888	7590	04/03/2006	EXAMINER	
HEDMAN & COSTIGAN P.C. 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036			LUKTON, DAVID	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	<b>Application No.</b> 10/666,072	<b>Applicant(s)</b> COURTIN ET AL.	
	<b>Examiner</b> David Lukton	<b>Art Unit</b> 1654	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 22 March 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
 b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☒ They raise the issue of new matter (see NOTE below);  
 (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see accompanying sheets. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: none.  
 Claim(s) objected to: none.  
 Claim(s) rejected: 34-38,40-43,50 and 51.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see accompanying sheets.  
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
 13. ☐ Other: \_\_\_\_\_.

Advisory Action

Claims 34-38, 40-43, 50, 51 remain pending.

The amendment filed 3/22/06 will not be entered, for the following reasons:

a ) The amendment to claim 43 attempts to modify the structural formula in piecemeal fashion, i.e., rather than providing a single structure, applicants have attempted to modify certain functional groups thereon. However, while applicants' intentions are clear to the examiner, they may not be clear to the persons responsible for printing the final document. The potential for error in the printing of the final document is substantial. For this reason alone the amendment will not be entered. The best option would be to cancel claim 43 and replace it with a new claim (e.g., claim 53).

b ) Another reason for not entering the amendment is that there is no descriptive support for "pharmaceutical carrier" in claim 50.

c ) A third reason for not entering the amendment is that claim 41 would not be subgeneric to (or properly dependent on) claim 51. Claim 51 is drawn to a method of using a compound, whereas claim 41 is drawn to a method of using a composition. If a person is practicing the method of claim 51, the method of claim 41 is thereby excluded. A person who is in possession of a single, pure compound is not in possession of a composition that contains that compound.



The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41 and 51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 51 recites the phrase “pharmaceutical preparation in the form of a solution”. There does not appear to be descriptive support for this. Since the amendment is not being entered, this rejection is maintained. However, if entered, the amendment would overcome this rejection.

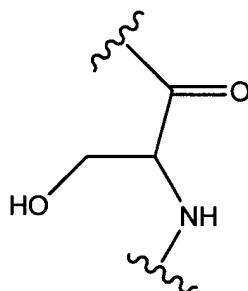


Claims 34-38, 40-43, 50, 51 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- As indicated previously, claim 38 recites that the compound in question is administered not as such, but rather as a composition. Accordingly, claim 38 is not properly dependent on claim 34 or on claim 43, since both of these claims (34 and 43) are drawn to a compound or to a method of using a compound. As the amendment is not being entered, this ground of rejection is maintained. And even if the amendment were to be entered, this ground of rejection would still apply. Claim 34 is drawn to the use of a compound, not a composition; proposed claim 38 mandates the use of an injectable preparation. As such, proposed claim 38 is not properly dependent on claim 34.
- Claim 41 recites the phrase “said solution”; this phrase lacks antecedent basis. Since the amendment is not being entered, this ground of rejection is maintained.
- Claim 50 is drawn to a composition that comprises a compound. The term “composition” mandates that at least one other compound be present,

or else that a carrier must be present. The claim is thus indefinite as to the nature or identity of that second compound or component. The same defect afflicts claim 51. Since the amendment is not being entered, this ground of rejection is maintained.

- In claim 43, "Z" can correspond to just one substituent group. Accordingly, "Z" should be eliminated from the claim. The same applies to variable R<sub>4</sub>. Since the amendment is not being entered, this ground of rejection is maintained.
- In the compound of claim 43, a serine is present. The side chain is, of course, -CH<sub>2</sub>OH. However, the hydrogen atom shown is superfluous, and should be eliminated, i.e., the following can be used:



Since the amendment is not being entered, this ground of rejection is maintained.

- In claim 43, variables R<sub>2</sub>, R<sub>3</sub> and R<sub>4</sub> are recited, wherein the number (2, 3 or 4) appears as a subscript. In the definition of the variables, none of variables R<sub>2</sub>, R<sub>3</sub> and R<sub>4</sub> is defined. Instead, variables R2, R3 and R3 have been defined. Consistency should be maintained. Since the amendment is not being entered, this ground of rejection is maintained.
- In claim 43, the phrase "or a pharmaceutically acceptable acid addition salt" should be preceded by a semicolon. Since the amendment is not being entered, this ground of rejection is maintained.



Applicants are requested to note that in claim 38, the phrase “compound **of** its acid addition salt” probably should instead be the following:

compound **or** its acid addition salt

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON, PH.D.  
PRIMARY EXAMINER